

MedDorna

Ambulatory Cardiac Monitor

User's Manual

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Ambulatory Cardiac Monitor

User's Manual

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1. Introduction to the Ambulatory Cardiac Monitor

Thank you for purchasing Ambulatory Cardiac Monitor. The Ambulatory Cardiac Monitor User's Manual was designed to quickly get you started using Ambulatory Cardiac Monitor.

This section explains the indications for use of Ambulatory Cardiac Monitor, along with special warnings, requirements, and installation information for using the software. The remainder of this manual provides more specific information about the hardware and software included with this product, as well as appendices giving reference information.

Please make sure to review the Warranty and License Agreement section (Appendix A) specifying the hardware warranty and software license information. Using any part of the software indicates that you accept the terms of these agreements.

1.1. Indications for use

Ambulatory Cardiac Monitor is intended to be used for the recording, displaying and reviewing of ECG signals with the purpose of analyzing cardiac rhythms and performing quick patient assessments.

WARNING FOR PACEMAKER PATIENTS:

Ambulatory Cardiac Monitor may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon the heart rate display. Keep pacemaker patients under close surveillance. See Appendix D of this manual for disclosure of the pacemaker pulse rejection capability of Ambulatory Cardiac Monitor.

1.2. System requirements

The Ambulatory Cardiac Monitor software consists of two software components: Ambulatory Cardiac Recorder software for Pocket PC handheld and Ambulatory Cardiac Viewer software for Windows PC.

To install and use the components of the Ambulatory Cardiac Monitor software, your computer system must meet the following requirements:

Pocket PC handheld requirements:

- Windows Mobile 2003 OS version or later
- 6 MB RAM (memory) free
- Integrated Bluetooth port providing support for virtual serial port connection
- Secure Digital (SD) card slot
- Secure Digital card with at least 16 Mb memory available

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Windows PC requirements:

Windows XP or Windows 2000 OS
Pentium III - compatible PC or higher
At least 16 Mb RAM available
At least 100 Mb of free hard disk space
VGA monitor or better
CD-ROM drive
SD card reader

Note: Non-MedDorna, LLC software running under Windows is not supported and may disrupt the proper operation of Ambulatory Cardiac Monitor Viewer software.

1.3. Software installation

The following instructions guide you through installing the Ambulatory Cardiac Monitor software from the CD-ROM which is included with the Ambulatory Cardiac Monitor product. After installation, on-line help is available under the Help menu item in the Ambulatory Cardiac Recorder software or the Help menu item in the Ambulatory Cardiac Viewer application.

To install Ambulatory Cardiac Monitor software:

1. Exit any open programs, including those that run automatically at start-up such as Microsoft Office, and disable any virus-scanning software.
2. Insert the Ambulatory Cardiac Monitor CD-ROM into the computer's CD-ROM drive.
3. Insert blank SD card into SD card reader. If SD card is not blank, all files on it will be deleted!
4. On some computers, this will automatically start the setup program. If the setup program does not start after 1 minute, open **autorun.exe** from the CD-ROM using Windows Explorer.
5. Follow the on-screen instructions to start the installation.
6. Once "Select Features" installation page appears, select any of the following components to be installed:
 - Ambulatory Cardiac Viewer
 - Ambulatory Cardiac RecorderBy default both options shall be selected.
7. Continue installation according to on-screen instructions.
8. Once installation on PC is finished, remove SD card from the card reader.
9. Insert SD card in Pocket PC handheld SD slot.

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10. Turn Pocket PC handheld on.
11. Click "Start" menu on top of the screen.
12. Select "File Explorer" menu option.
13. Click "My Device" menu option.
14. Select "CF Card" folder.
15. Click "MedDorna ACR" icon.
16. Follow the on-screen instructions to complete the installation.

1.4 Upgrade information

From time to time, new versions of the Ambulatory Cardiac Monitor software will be released. Some of these releases will contain new capabilities from the suggestions of users like you. Make sure to check the MedDorna, LLC web site for new releases. Software on MedDorna's web site will include installation or upgrade directions.

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2. Ambulatory Cardiac Monitor Hardware

The Ambulatory Cardiac Monitor hardware is a part of the Ambulatory Cardiac Recorder component consisting of the Ambulatory Cardiac Recorder device and Pocket PC handheld.

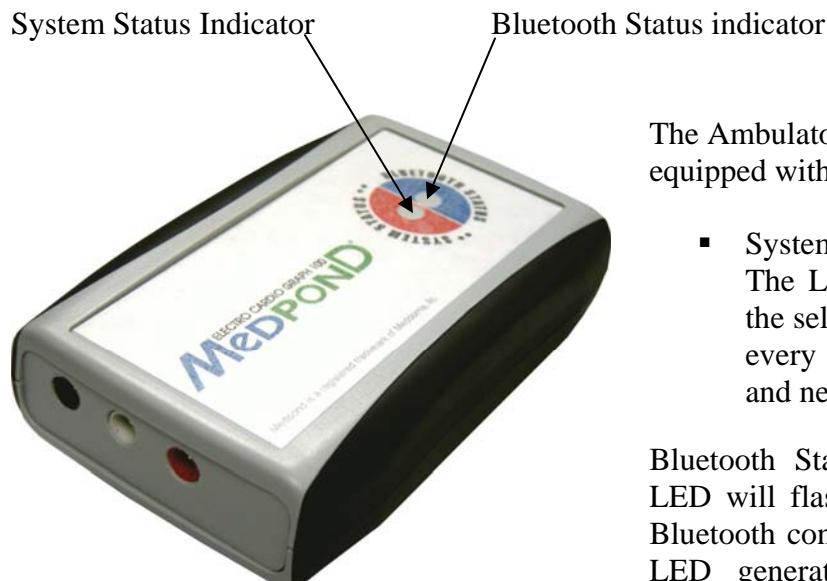
The Ambulatory Cardiac Recorder device (MedDorna Wireless PRN ECG) has features which make it exceptional as a portable ECG device. The unit is designed for quick access and quick assessment. There are no buttons, switches, or controls - everything is controlled from the Pocket PC handheld via Bluetooth connection. No latex is used anywhere within the Ambulatory Cardiac Recorder device to help avoid allergic reactions from medical personnel and patients.

2.1. Hardware features

Three ECG electrode lead connectors are located in front of the Ambulatory Cardiac Recorder device.

Connect Red ECG electrode lead wire (LL) to the Red input connector, Black (LA) to the Black input connector and White electrode lead wire (RA) to the Black input connector.

When you completed patient monitoring, disconnect the electrodes, clean the electrode lead wires if necessary, and put them into plastic bag.



The Ambulatory Cardiac Recorder device is equipped with two status indicators:

- System Status Indicator (Red LED). The LED will flash every 1 second if the self test has failed. It will flash once every 10 seconds if batteries are low and need to be recharged or replaced.

Bluetooth Status Indicator (Blue LED) The LED will flash once every 10 seconds when Bluetooth connection is in standby mode. The LED generates 2 short flashes every 10 seconds when communication with host computer has been established and 2 short flashes every 3 seconds when device in operating mode and sending data to host through Bluetooth channel.

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2.2. Battery and battery installation



The battery cover slides down to expose the battery compartment. The battery used in the Ambulatory Cardiac Recorder device was selected to be a balance between long-life, light weight, and easy availability. Ambulatory Cardiac Recorder device uses standard 2 standard Ni-MH AA rechargeable batteries that are available in most drug stores, hardware stores, grocery stores, or on the Internet.

Ambulatory Cardiac Recorder device uses battery power very sparingly. It continuously monitors its own use and shuts down parts of the circuit when they aren't needed. You can expect over two weeks of heavy use (assessing 7 patients a day, recording 5 strips for each patient) from a single battery. It is strongly recommended that you carry a spare battery with you, especially if the device is used outside a medical facility. The Ambulatory Cardiac Recorder application will give a low-battery warning when there is approximately 2 days of power remaining in the battery. You should replace the battery whenever this low-battery indicator is displayed to avoid malfunctioning of the unit.

Warning: Only use the model of battery indicated and follow all battery labeling instructions. Install the battery prior to the expiration indicated on the battery labeling.

Please observe the following precautions to keep the battery in good condition.

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Storage:

- Avoid storing batteries at unusually high or low temperatures. Batteries are best when used and stored between -40°C to 70°C (-40°F to 158°F).
- Keep batteries in a low-humidity location with little temperature variation.
- Keep batteries away from direct sunlight.

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3. Ambulatory Cardiac Monitor Software

There are two software components in the Ambulatory Cardiac Monitor software:

1. The Ambulance Cardiac Recorder application runs on the Pocket PC handheld and interacts with the Ambulatory Cardiac Recorder device to monitor and record ECG data.
2. The Ambulatory Cardiac Viewer application for Windows opens data that was transferred from a Pocket PC handheld and allows you to build a report, print a report, and exchange ECG strips with other Ambulatory Cardiac Viewer applications.

3.1. Ambulatory Cardiac Recorder

3.1.1. Start up the Ambulance Cardiac Recorder Software

The Ambulance Cardiac Recorder software is installed and resides in the Pocket PC handheld RAM.

You should do the following procedure to load the software:

1. Click “Start” on the Pocket PC handheld taskbar;
2. Select “Programs” from the system menu;
3. Scroll the “Program” window to find “Ambulance Cardiac Recorder” icon and click it.

Once the Ambulance Cardiac Recorder software starts:

1. It checks if SD card is inserted. If it is not inserted, the following message is displayed:



Click “OK” button to close this message.

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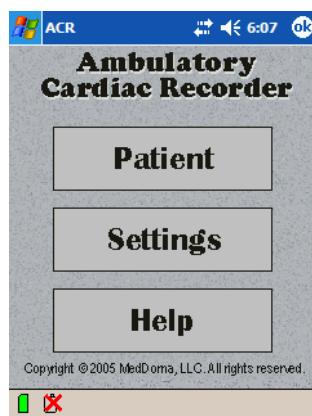
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2. If SD card is inserted, the software checks if a newer software update file is present on it. If such file is found the following message is displayed:

A newer version of Ambulatory Cardiac Recorder software is detected. You can close this program and install new version manually or continue with the current version. Continue?

Click “No” button to close the software to manually install the new version from SD card.

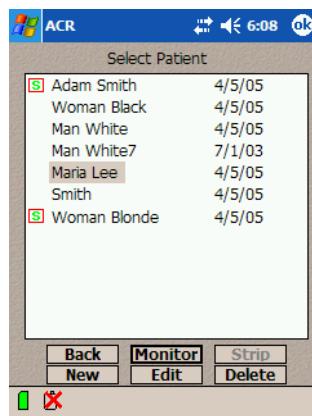
Click “Yes” button to continue starting the software. The following screen is displayed then:



There are three main system modes:

1. Patient
2. Settings
3. Help

Click “Patient” button to access the main functionality of the Ambulance Cardiac Recorder software. This opens the following screen:



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Each list item displays patient name, date of creation of the patient record. To the left of patient name there might be a small icon displayed that indicates that this patient record has at least one ECG strip recorded in it.

Below the patient list there are six buttons displayed:

“Back”	Return to the main menu
“Monitor”	Initiate ECG signal acquisition and recording for selected patient
“Strip”	View ECG strips recorded in selected patient record
“New”	Create new patient record
“Edit”	Modify selected patient information
“Delete”	Delete selected patient record

3.1.2. Add New Patient Record

The Ambulance Cardiac Recorder software stores multiple patient records in its internal database. All patient records available in the database are displayed on the patient list.

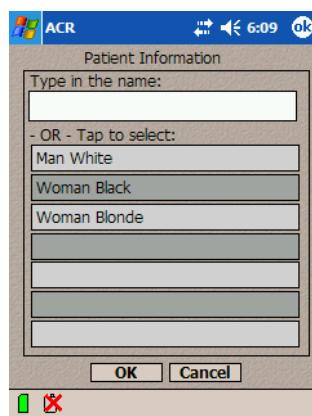
To add a new patient record you should click the “New” button below the patient list. No selection from the patient list is required.

During this procedure the Ambulance Cardiac Recorder software opens the database file and performs certain database operations. If the software is unable to open the database file, the following message is displayed:

Unable to open the database file on SD card. Please check your SD card.

Click OK to close this message box.

If database was successfully open, the software displays the following dialog box:



You should quickly input a new patient name using this dialog box.

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The patient name can be keyed in using an on-screen keyboard. Since the Ambulance Cardiac Recorder system could be used in emergency situation a more generic predetermined patient name can be selected from the list of up to 7 such names to save time. You can configure the list of such “quick names” using one of the “Settings” procedures.

Click “OK” button to complete creation of the new patient record. This displays the list of patients with a new patient record added to the list.

If data entered in the text input field has inappropriate format, e.g. wrong symbols entered the following message will appear:

Incorrect data entered.

If data is not entered in any required data field, the following message will appear:



Upon clicking “OK” the software updates the database file. If database operation fails, the following message is displayed:

Failed to add new patient record.

Click “OK” button to close this message box.

Click “Cancel” button to abort this procedure. This brings the unchanged patient list screen.

3.1.3. Edit Patient Record

The Ambulance Cardiac Recorder software stores multiple patient records in its internal database. The list of patient records in this database is displayed on the list shown above in Section 3.1.1.

Select patient name from the list, then click “Edit” button below the patient list to edit the information in existing patient record.

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This displays the same dialog box as in adding new patient records. However the patient name field is populated with the name currently stored in the record.

The entire procedure of editing patient information is identical to such when creating a new patient record.

Upon saving changes in the patient record the software updates the database file. If database operation fails, the following message is displayed:

Failed to update patient record.

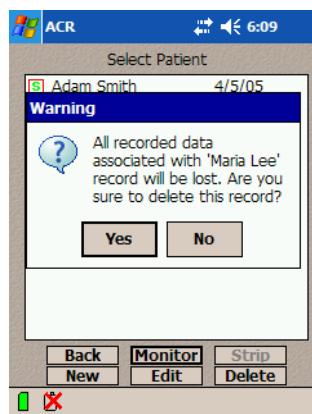
Click “OK” button to close this message box.

3.2.1.4. Delete Patient Record

The Ambulance Cardiac Recorder software stores multiple patient records in its internal database. The list of patient records in this database is displayed on the list shown above in Section 3.1.1.

Select patient name from the list, then click “Delete” button below the patient list to delete certain patient record.

This will display a message box asking to confirm deletion:



Click “Yes” button to delete selected record. This will bring the display to the previously viewed screen with the updated patient list.

This operation updates the database file. If database operation fails, the following message shall be displayed:

Failed to delete patient record.

Click “OK” button to close this message box.

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Click “No” to abort deletion.

3.1.5. Monitor / Record ECG Signal

When patient is ready for monitoring ECG signal (ECG leads were placed on patient and connected to the ECG recording device), select patient name from the list and click “Monitor” button to start ECG signal acquisition.

The “Monitor” button is not available until patient name is selected from the list.

Once “Monitor” button is clicked, the following procedure takes place:

- 1) The software checks if SD card is inserted. If it is missing, the following message is displayed:

SD Card is missing. Please insert the card to be able to monitor patient.

Click “OK” button to close this message.

- 2) The software attempts to connect to the ECG recorder device. If connection fails, the following message is displayed:

Unable to connect to ECG recorder. Please refer to the manual to troubleshoot the device.

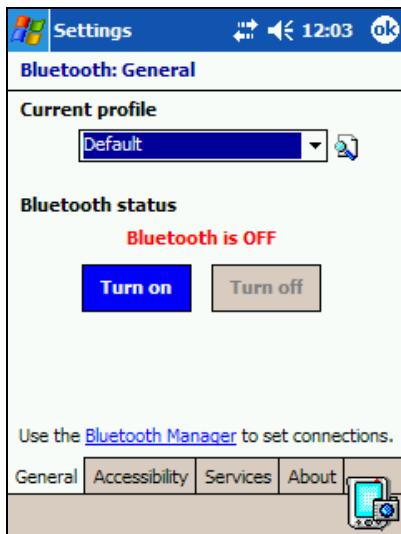
Click “OK” button to close this message box.

If connection fails, it is very likely that Bluetooth port is not turned on or configured in your Pocket PC handheld. To turn it on and / or configure please do the following steps:

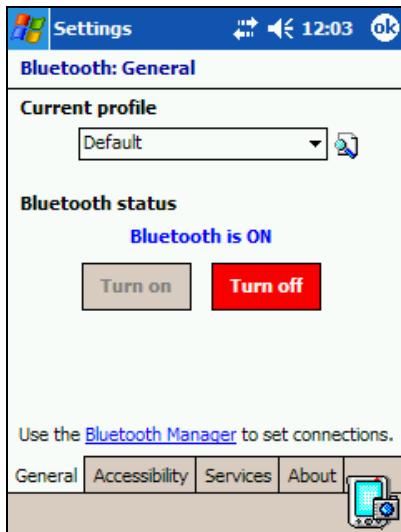
1. Click “Start” button on top of your handheld screen.
2. Select “Settings” menu item from the drop-down menu.
3. Select “System” tab at the bottom of “Settings” screen.
4. Click “Bluetooth” icon.
5. The following screen should appear:

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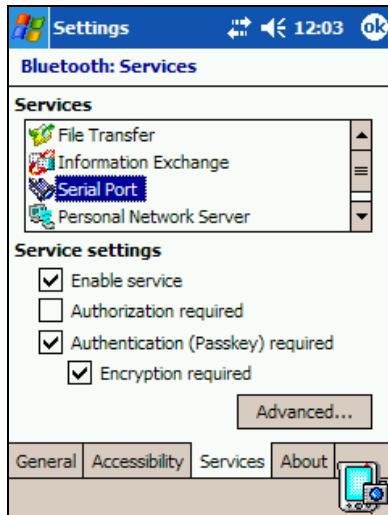
6. Click "Turn on" button. This should start blue LED blinking on your handheld. The screen should turn into:



7. Select "Services" tab at the bottom to get the following screen:

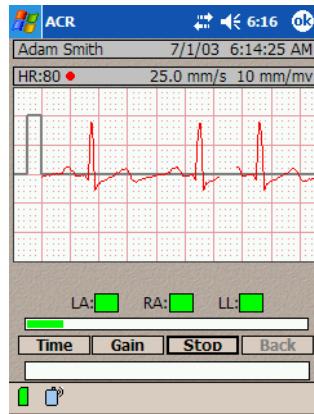
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8. Select “Serial Port” from the list of services.
9. Make sure “Enable service”, “Authentication (Passkey) required” and “Encryption required” checkboxes are set and “Authorization required” checkbox is cleared.
10. Click “OK” to close ‘Bluetooth Settings’ window.
11. Click “X” to close “Settings” window.

If everything is normal, the following screen appears:



The following objects are displayed on this screen from top to bottom:

- 1) Current patient name, actual date and time.
- 2) Actual Heart Rate (HR). To the right of HR reading a small “heart” icon shall be blinking with each heartbeat detected.
- 3) Current settings of horizontal and vertical scales of the ECG.

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- 4) ECG signal graph updating in real-time from left to right as on oscilloscope screen.
- 5) Three electrode impedance indicators: LA, RA and LL.
- 6) ECG recording progress indicator.
- 7) Message bar.
- 8) Command buttons:
 - A) "Time Scale" – to adjust horizontal scale of the ECG graph to one of the following options:
 - i) 12.5 mm/sec
 - ii) 25 mm/sec
 - iii) 50 mm/sec
 - B) "Amplitude Scale" – to adjust vertical scale of the ECG graph to one of the following options:
 - i) 5 mm/mV
 - ii) 10 mm/mV
 - C) "Record" – to initiate ECG recording;
 - D) "Back" – to abort ECG monitoring and return to patient list.

The recording process is off when ECG monitoring starts. The software checks for the amount of SD card memory available for saving ECG data. If it is not sufficient, then "No memory available on PDA to continue recording" message is displayed on the message bar and "Record" button becomes disabled.

Click "Record" button to initiate recording. Once recording starts the "Record" button is renamed to "Stop".

When recording is turned on, the "Back" button shall become disabled.

The recording will automatically stop after 30 seconds of recording.

Click "Stop" button to prematurely stop ECG recording. This turns "Stop" button name back to "Record" and enables "Back" button.

Upon completion of ECG recording the process is automatically stopped and ECG data saved in the database file. The software checks for presence of SD card. If it is not inserted, the following message is displayed:

SD Card is missing. Please insert the card to be able to save data.

Insert SD card and click "OK" button to close this message box, save data and proceed. The software will recheck the SD card before saving data. It will do up to 10 attempts to save data, if it is not done, then current ECG recording will be lost. The software displays the following message in this case:

Failed to save ECG strip.

Click "OK" button to close this message box.

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Upon completion of ECG recording the monitoring automatically stops and the software brings up an updated list of patients. If selected patient did not have ECG strips previously recorded, this time a special icon appears before patient name indicating that there are ECG strips recorded for this patient.

Click the “Time Scale” button to adjust horizontal scale of the ECG graph to one of the following options:

- 12.5 mm/sec
- 25 mm/sec
- 50 mm/sec

Click the “Amplitude Scale” button to adjust vertical scale of the ECG graph to one of the following options:

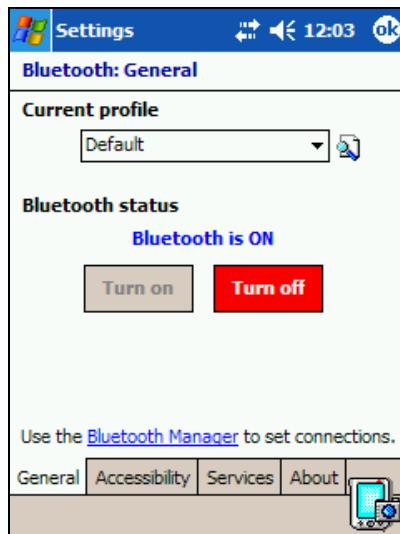
- 5 mm/mV
- 10 mm/mV

Upon completion of patient monitoring you may want to turn Bluetooth off in your Pocket PC handheld:

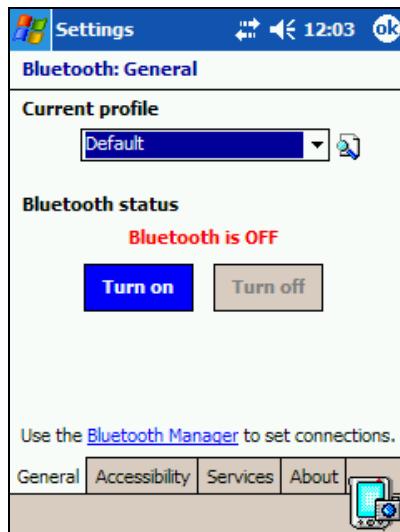
1. Click “Start” button on top of your handheld screen.
2. Select “Settings” menu item from the drop-down menu.
3. Select “System” tab at the bottom of “Settings” screen.
4. Click “Bluetooth” icon.
5. The following screen should appear:

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6. Click “Turn off” button. This should stop blue LED blinking on your handheld. The screen should turn into:



7. Click “OK” to close “Bluetooth Settings” window.
8. Click “X” to close “Settings” window.

3.1.6. View ECG Strips

You may wish to observe ECG strips recorded in patient records. If such strips are available in any particular record, a small icon is displayed to the left of patient name in the list of patients.

Select patient record from the list that has indication that there are ECG strips in the record, then click “Strip” button.

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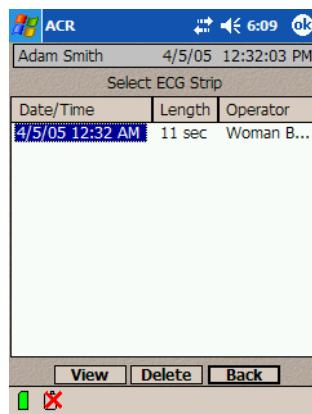
If patient record is selected that does not have indication of presence of ECG strips stored, then “Strip” button is disabled preventing from opening view of such record.

Once “Strip” button is clicked the software checks if SD card is inserted. If it is missing, the following message is displayed:

SD Card is missing. Please insert the card to continue.

Click “OK” button to close this message.

If SD card is present, the following screen appears:



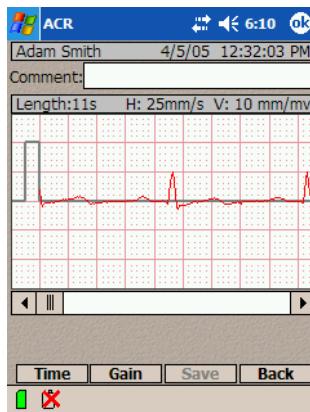
It displays the list of ECG strips stored in selected patient record. Each list item identifies the date and time the strip was recorded, the length of strip recorded (in seconds) and the name of operator who made this recording.

- “View” Display selected ECG strip
- “Delete” Delete selected ECG strip
- “Back” Return to patient list

Select one strip from the list, then click “View” button. This will display the following screen:

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The following objects will be displayed on this screen from top to bottom:

- 1) Current patient name, the date and time when this strip was recorded.
- 2) Strip comment entry field.
- 3) Length of current ECG strip.
- 4) Current settings of horizontal and vertical scales of the ECG.
- 5) Standard ECG strip displayed according to current settings of its horizontal and vertical scales.
- 6) Horizontal scroll bar for scrolling ECG strip back and forth.
- 7) Command buttons:
 - A) "Time Scale" – to adjust horizontal scale of the ECG graph to one of the following options:
 - i) 10 mm/sec
 - ii) 25 mm/sec
 - iii) 50 mm/sec
 - B) "Amplitude Scale" – to adjust vertical scale of the ECG graph to one of the following options:
 - i) 5 mm/mV
 - ii) 10 mm/mV
 - C) "Save" – to save comments that could be added to this strip (see below);
 - D) "Back" – to return to strip list.

When viewing ECG strip scroll the strip back and forth using the standard horizontal scroll bar. Use the left and right arrow buttons to scroll the strip backward or forward with 1 sec step. Drag the slider button to the left or right to quickly scroll the strip.

Click the "Time Scale" button to adjust horizontal scale of the ECG graph to one of the following options:

- 12.5 mm/sec
- 25 mm/sec
- 50 mm/sec

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Click the “Amplitude Scale” button to adjust vertical scale of the ECG graph to one of the following options:

- 5 mm/mV
- 10 mm/mV

While viewing ECG strip you can type in a short comment that will be stored along with this strip. By default the “Save” button is disabled. If such comment is entered or modified, the “Save” button becomes enabled. Click “Save” button to save the comment.

When “Save” button is clicked the software checks if SD card is present. If not the following message is displayed:

SD Card is missing. Please insert the card to continue.

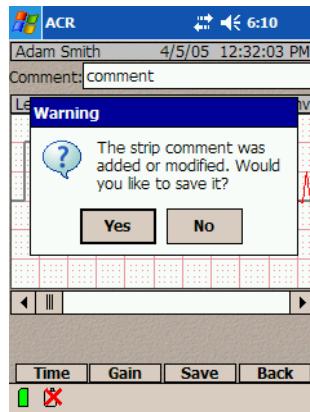
Click “OK” button to close this message.

If saving procedure fails, the following message is displayed:

Failed to save comments.

Click “OK” button to close this message box.

If a strip comment was entered or modified and you click “Back” button to go back to the strip list, the software displays a warning message:



Click “Yes” button in the message box to save the comment.

Click “No” button in the message box to drop the comment added or modified.

3.1.7. Delete ECG Strips

You may need to delete certain ECG strips from the patient record.

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Do the following to delete selected strip:

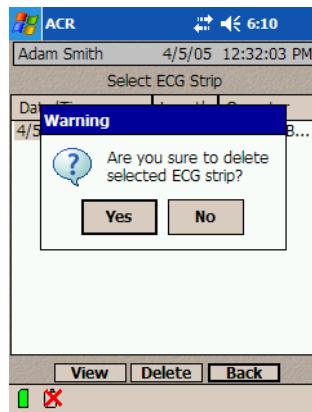
1. Select patient name from the list of patients.
2. Click “Strip” button.
3. Select strip to be deleted from the list of strips in the selected patient record.
4. Click “Delete” button.

During this procedure the Ambulatory Cardiac Recorder software opens the database file and performs certain database operations. If the software is unable to open the database file, the following message is displayed:

Unable to open the database file on SD card. Please check your SD card.

Click OK to close this message box.

Once “Delete” button is clicked the software will prompt you to confirm the deletion:



Click “Yes” button in the message box to confirm deletion of the strip.

Click “No” button in the message box to abort deletion.

3.1.8. Transfer ECG Strips to Ambulatory Cardiac Viewer

You can transfer patient records from the Ambulance Cardiac Recorder system component to the Ambulance Cardiac Viewer system component by adding those records and ECG strips to the Ambulance Cardiac Viewer internal database.

The transferred records will be automatically deleted from the Ambulance Cardiac Recorder upon successful transfer to the Ambulance Cardiac Viewer.

The internal Ambulance Cardiac Recorder database is stored on SD card inserted into Pocket PC handheld where Ambulance Cardiac Recorder resides.

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When you need to transfer data to the Ambulance Cardiac Viewer, the SD card shall be pulled out of SD slot in the Pocket PC handheld and passed to the Ambulance Cardiac Viewer. Insert the SD card into SD card reader connected to PC where the Ambulance Cardiac Viewer system component resides. The Ambulance Cardiac Viewer software will be used to perform data transfer.

Upon successful data transfer the database on SD card is automatically emptied by the Ambulance Cardiac Viewer software. Take the SD card back and insert it into SD slot in the Pocket PC handheld.

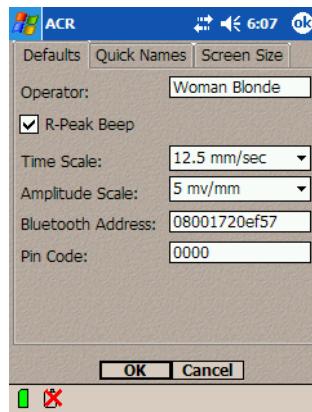
As long as patient database on SD card is empty, the Ambulance Cardiac Recorder software displays an empty patient list when it starts.

Please be very cautious not to remove SD card, when SD card usage indicator displayed on the software title bar. This is especially important during ECG recording process!

3.1.9. Configure Ambulance Cardiac Recorder Default Settings

The Ambulance Cardiac Recorder software operates using various system settings that can be configured to specific default values.

Click the “Settings” button in the main program menu to configure default settings. The following dialog box appears:



Select “Default” tab if it is not selected yet.

Type your own name in the “Operator” field using a free text format. A simple first name, last name, nickname or a full name could be used for your identification in the system.

Set an “R-Peak Beep” checkbox to enable sound beeps associated with each heartbeat detected by the system.

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Set a default Time (Horizontal) Scale to one of the following options:

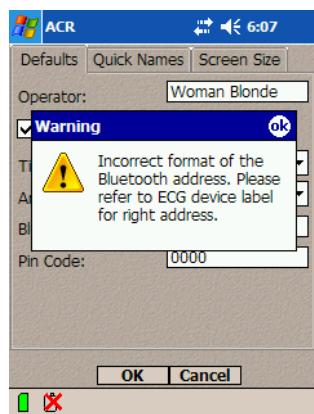
- 12.5 mm/sec
- 25 mm/sec
- 50 mm/sec

Set a default Amplitude (Vertical) Scale to one of the following options:

- 5 mm/mV
- 10 mm/mV

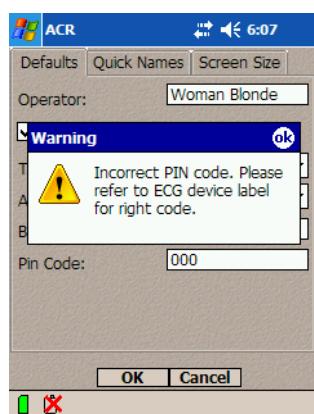
Click “OK” button to store and enable new default settings and return to the main screen. The software checks if Bluetooth address consists of 12 hexadecimal symbols (0 to 9 and A to F) and PIN code consists of 4 numerical symbols (0 to 9).

If Bluetooth address entered is incorrect, the following message is displayed:



Click “OK” button to close this message box and correct the entry.

If PIN code entered is incorrect, the following message is displayed:



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Click “OK” button to close this message box and correct the entry.

Click “Cancel” button to drop all changes made and return to the main screen.

3.1.10. Configure Quick Patient Names

When you have to input a new patient name, it could be an emergency situation that requires starting ECG recording as soon as possible. The hardware capabilities of Pocket PC handheld make typing long names rather difficult. In such situation using more generic predetermined names by selection from the list will save time.

Click the “Settings” button in the main program menu to configure the list of quick patient names. This brings up the dialog box described in Section 3.1.9.

Select “Quick Names” tab and the following dialog box appears:



Type the generic names in any of seven data fields.

Once the names are entered click the “OK” button to save changes and return to the main screen.

Click “Cancel” button to drop all changes made and return to the main screen.

3.1.11. Configure Screen Size Settings

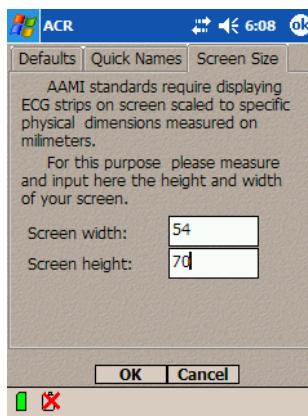
The AAMI standards require displaying ECG strips on computer screen in very specific physical dimensions, e.g. the total height of the strip must be precisely 30 mm, the ECG signal must be shown in certain scales (see below).

This requirement forces to use specific information about screen physical dimensions in connection to its current resolution. Modern monitors are unable to supply such information by the software requests. Because of that you have to measure physical dimensions of the viewable part of your screen and input measurement into the software.

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Click the “Settings” button in the main program menu to configure the size of screen. This brings up the dialog box described in Section 3.1.9.

Select the “Screen Size” tab and the following dialog box appears:



Type the width and height of the screen in millimeters.

Click “OK” button to save changes and return to the main screen. The software checks if any of those entries are within 30 to 100 millimeters.

Click “Cancel” button to drop all changes made and return to the main screen.

3.1.12. View Ambulance Cardiac Recorder Onscreen Help

The software has built-in quick help describing all important aspects of the system functioning.

Click the “Help” button in the main program menu to open a standard Windows CE help window.

The help system has a table of content, from which you can open any help topic.

3.1.13. Exit Ambulance Cardiac Recorder Software

Click the “Exit” button in the upper right corner of the screen to close the software.

If this button is clicked in monitoring mode whether recording is activated or not, the following message box appears:

Unable to exit the program when patient is being monitored. Please stop monitoring first then exit the program.

Click “OK” button to close this message box.

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3.1.14. Ambulance Cardiac Recorder Software Status Indicators

The Ambulance Cardiac Recorder software displays two iconic indicators showing current status of the following conditions:

- SD Card Status:
 - SD Card Inserted
 - SD Card Not Inserted
- Bluetooth Connection:
 - ECG Recorder Not Connected
 - ECG Recorder Connected in Standby Mode
 - ECG Recorder Connected in Operational Mode
 - ECG Recorder Low Battery Alarm

Both indicators are displayed on the bottom status bar.

3.2. Ambulatory Cardiac Viewer

3.2.1. Start up the Ambulatory Cardiac Viewer Software

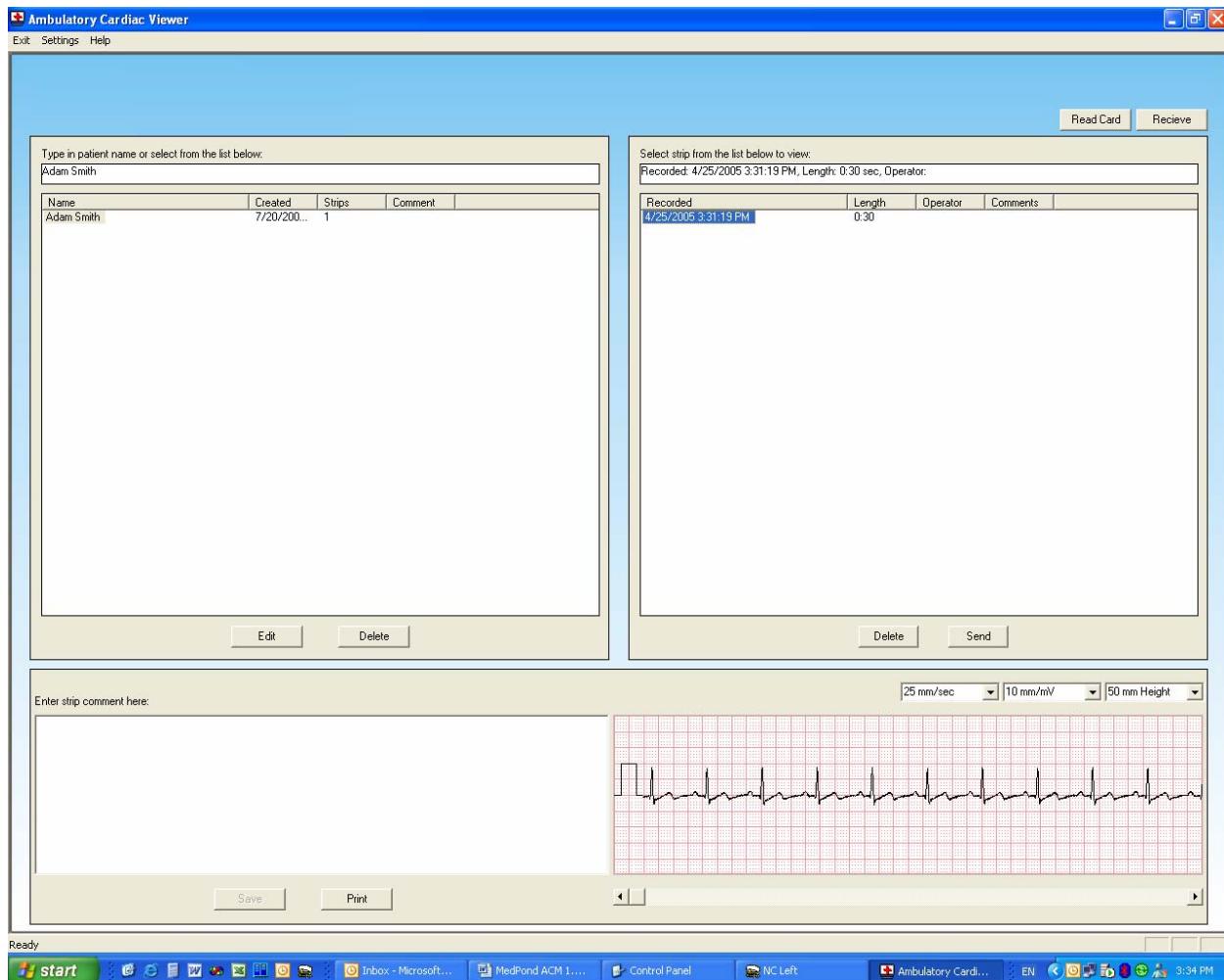
The Ambulatory Cardiac Viewer software is installed and resides on PC (desktop or laptop) operating under Windows XP operating system.

Click the “Ambulatory Cardiac Viewer” shortcut icon on the desktop screen to load the software.

Once the Ambulatory Cardiac Viewer software starts, the following screen is displayed:

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3.2.2. Read ECG Strips from SD Card

When transferring patient records with ECG strips from the Ambulatory Cardiac Recorder stored on SD Card, all such records will be moved from the card into Ambulatory Cardiac Viewer database.

Insert SD card into the SD card reader connected to PC where the Ambulatory Cardiac Viewer software is installed.

Click “Read Card” button to access the card. If card is inserted and accessible, the Ambulatory Cardiac Viewer software automatically performs the following transaction:

- Access SD Card content;
- Identify the Ambulatory Cardiac Recorder database file on SD Card;
- Read Ambulatory Cardiac Recorder database content;
- Transfer data from the Ambulatory Cardiac Recorder database to the Ambulatory Cardiac Viewer database;

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- Remove transferred data from the Ambulatory Cardiac Recorder database.

While performing this transaction, the Ambulatory Cardiac Viewer software displays the progress indicator showing its completion. Upon completion the following message box appears:

All patient data was successfully transferred from the SD card. You may remove the card from the card reader.

Click OK button to close this message box.

If any of these transaction steps are not complete, the whole transaction is not complete and the system will be reverted to its original state which was before the transaction. One of the following messages will be displayed depending on which operation has failed:

- Unable to access SD Card or Ambulatory Cardiac Recorder database file found on SD Card.
- Unable to read the Ambulatory Cardiac Recorder database content.
- Failed to transfer data from the Ambulatory Cardiac Recorder database to the Ambulatory Cardiac Viewer database.
- Failed to remove transferred data from the Ambulatory Cardiac Recorder database.

Click OK button to close this message box.

Once the data is transferred to the Ambulatory Cardiac Viewer database, the list of patients on the Ambulatory Cardiac Viewer screen will be automatically updated.

3.2.3. Select Patient Record

Before any patient data can be accessed, such patient must be found and opened.

There are two ways to find and open patient record needed:

1. Using quick search of patient name;
2. Scrolling patient list and selecting patient name.

Each line on the patient list shows the following information:

- Patient name
- Date of creation of the patient record
- Number of ECG strips in the record
- Patient comment

All records on the list are alphabetically sorted by patient name. The names are not specifically formatted but used as they were entered in the Ambulatory Cardiac Recorder software or subsequently edited in the Ambulatory Cardiac Viewer software.

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To perform quick name search you should begin typing patient name into the text entry field above the patient list. With each letter typed in, the list of patient will automatically highlight the first name on it matching the sequence of letters typed in. This quickly navigates to the name you need. If the searched name is displayed highlighted, it is already selected and opened. If the searched name is not highlighted but visible on the list, click it to finish selection.

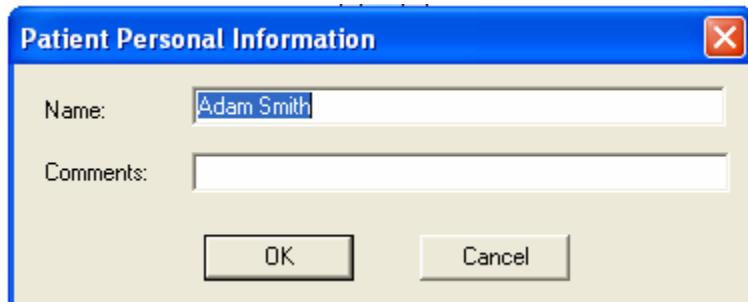
Alternatively you can scroll the list of patients up or down to find the name needed and then click it to highlight and make selection. Once the name is highlighted the record is open.

Once the patient record is open the list of ECG strips stored in it is displayed on the list of strips.

3.2.4. Edit Patient Information

Select an appropriate patient record as described in Section 3.2.3. to edit patient information.

Click the “Edit” button underneath the patient list. This brings the following dialog box:



Edit patient name if necessary.

You may enter or edit special comments associated with this patient if necessary. This data field may remain blank.

Click “OK” button to save changes. The dialog box will close and patient list will be updated accordingly.

Click “Cancel” button to drop changes made. The dialog box will close and patient list will remain unchanged.

3.2.5. Delete Patient Record

Select an appropriate patient record as described in Section 3.2.3. to delete certain patient record.

Then click “Delete” button underneath the patient list. This will display a message box asking to confirm deletion:

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All recorded data associated with “Patient Name” record will be lost. Are you sure to delete this record?

Click “Yes” button to delete selected record. The message box will close and patient list will be updated accordingly.

Click “No” to abort deletion. The message box will close and patient list will remain unchanged.

3.2.6. Select ECG Strip

Once patient record is opened, the list of ECG strips available in this record is displayed in the right part of the Ambulatory Cardiac Viewer screen.

Each line on the list displays the following information:

- Date and time when ECG strip was recorded
- Length of ECG strip in seconds
- Operator who recorded the strip
- Strip comment

All items on the list are sorted by the date and time.

Scroll the list if necessary and click a list item to highlight and select any ECG strip for further operation with it.

Once the strip is selected, its comment (if available) is displayed on the bottom left part of the Ambulatory Cardiac Viewer screen. The ECG strip is displayed on the bottom right part of the Ambulatory Cardiac Viewer screen.

3.2.7. View Selected ECG Strip

First select certain ECG strip from the list as described in Section 3.2.6. to view it.

Once the strip is selected, it is displayed in the bottom right section of the Ambulatory Cardiac Viewer screen.

The display of ECG signal is done according to current settings of the strip height, horizontal (time) and vertical (amplitude) scales. These settings are marked on top of the strip.

You can change the height of ECG strip and either of these scale settings using respective “Height”, “Time Scale” and “Amplitude Scale” selectors placed on top of the strip.

Use the “Height” selector to adjust the height of the ECG strip to one of the following options:

- 30 mm

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- 50 mm/sec

Use the “Time Scale” selector to adjust horizontal scale of the ECG strip to one of the following options:

- 12.5 mm/sec
- 25 mm/sec
- 50 mm/sec

Use the “Amplitude Scale” selector to adjust vertical scale of the ECG strip to one of the following options:

- 5 mm/mV
- 10 mm/mV
- 20 mm/mV (not available if the height is set to 30 mm)

When viewing ECG strip scroll the strip back and forth using the standard horizontal scroll bar. Use left and right arrow buttons scroll the strip backward or forward with 1 sec step. Drag the slider button to the left or right to quickly scroll the strip.

3.2.8. Edit ECG Strip Comment

Each ECG strip may have a special comment associated with it and entered by the operator in the Ambulatory Cardiac Recorder system.

To view and edit this comment select the strip from the list as described in Section 3.2.6.

Once the strip is selected its comment is shown in a special text input field in the bottom left section of the Ambulatory Cardiac Viewer screen.

Use the standard means to input or modify the comment.

Click “Save” button to save the changes.

If you attempt to select another strip after current strip comment was modified but not saved, the software will prompt you to save it:

The strip comment was added or modified. Would you like to save it?

Click “Yes” button in the message box to save the comment.

Click “No” button in the message box to drop the comment added or modified.

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3.2.9. Delete ECG Strip

You may need to delete certain ECG strips from the patient record.

To delete ECG strip select the strip from the list as described in Section 3.2.6.

Then click “Delete” button. The software will prompt you to confirm the deletion:

Are you sure to delete the selected ECG strip?

Click “Yes” button in the message box to confirm deletion of the strip. This will update the list of strips and first strip in the list becomes automatically selected.

Click “No” button in the message box to abort deletion.

3.2.10. Print ECG Strip Report

You can print a multiple-page report for a selected ECG strip. The printable report has a special portrait-type layout displaying the following information from top to bottom:

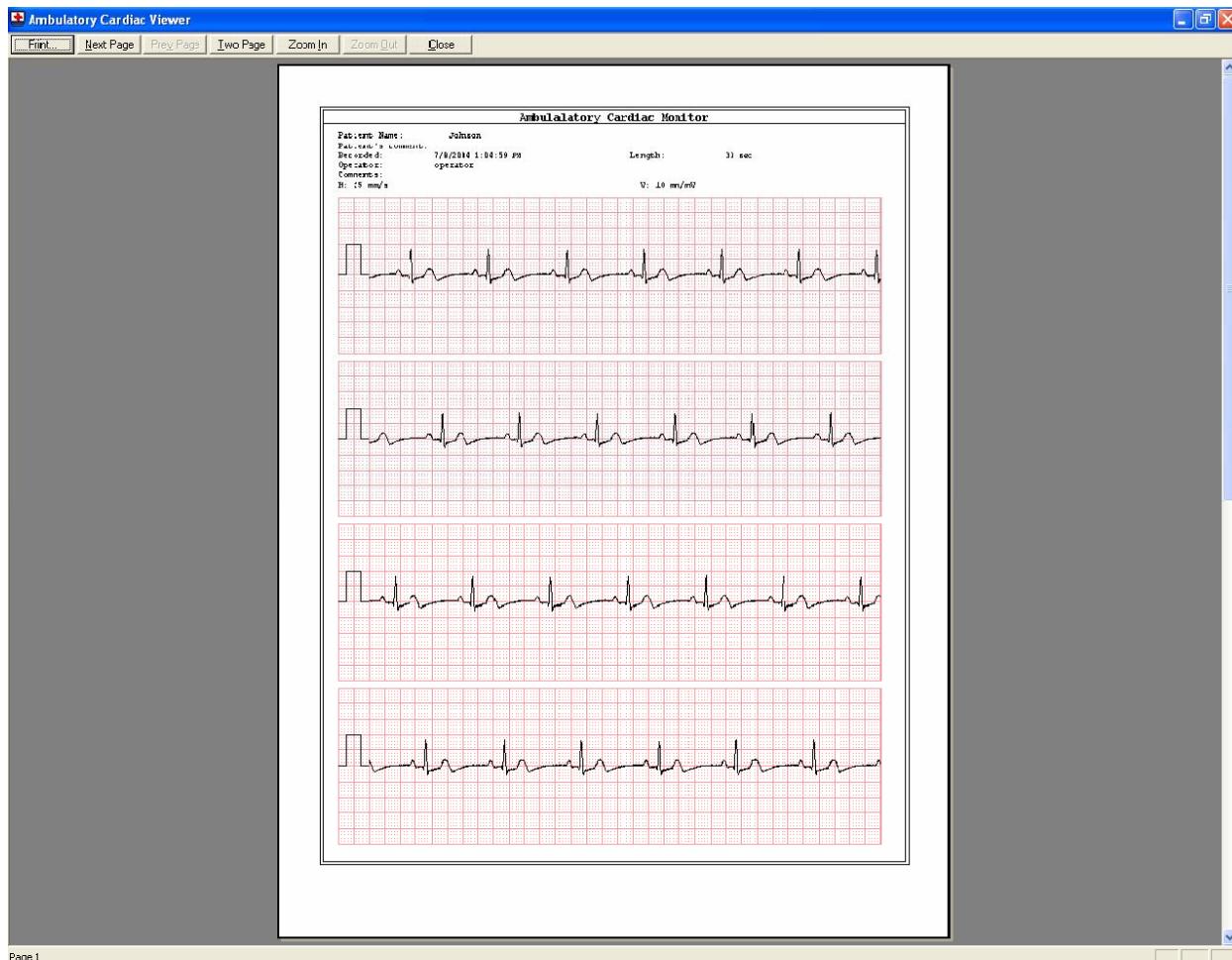
- Report title – “Ambulatory Cardiac Monitor”
- Patient name
- Operator
- Patient comment
- Date and time when ECG strip was recorded
- Length of strip
- Strip comment
- ECG strip image cut in number of sections to the width of report page and placed sequentially one below another.

To print such report select the strip from the list as described in Section 3.2.6.

Then click “Report” button. This will display the following report preview screen:

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The preview image shows the printable report layout as if it is printed on the paper sheet. The preview displays the page in “1x1” size.

Click “Zoom In” or “Zoom Out” buttons to change the size of the preview image.

Click “Print” button to initiate printing report page. Depending on printer installed on PC, there might be an additional dialog box appeared to set specific printer settings and special printing options. The user shall follow the on-screen instruction to complete printing.

Click “Prev Page” or “Next Page” buttons to move from one page of report to another. The actual number of pages depends on the length of ECG strip, current height of ECG strip and current setting of the time scale.

Click “Close” button to close print preview window and return to main screen.

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3.2.11. Send ECG Strip via Email

You can send any selected ECG strip to another user of the Ambulatory Cardiac Viewer software for review. The strip will be sent via email as a special binary file attached.

This feature assumes that you utilize any standard email client software like Microsoft Outlook, Outlook Express, etc. that allows for sending email messages with any binary files attached.

Upon creation of the binary file containing selected ECG strip in specified location (e.g. “My Documents” folder) you should open your email software, create a new email message, attach the file just created and send this mail to the destination. The process of sending file via email is beyond the scope of the Ambulatory Cardiac Viewer software.

The user of Ambulatory Cardiac Viewer software on the other end should use the “Receive Strip” feature (See description below) to import emailed strip into the system.

The file being sent contains all information necessary to identify the strip, such as:

- Patient name
- Patient comment
- Date and time ECG strip was recorded
- Length of strip
- Strip comment
- Name of operator recorded that strip

To send ECG strip select the strip from the list as described in Section 3.2.6.

Click “Send” button. The software opens a standard Windows “Save As” dialog box to specify file name and its location. The file has a standard “ACV” extension.

3.2.12. Receive ECG Strip via Email

You can receive an ECG strip for review sent by another user of the Ambulatory Cardiac Viewer software via email. The strip will be received via email as a special binary file attached to email message.

Upon receiving such message with a binary file attached save the file in a specified location (e.g. “My Documents” folder) using saving feature of your email software. The process of receiving email messages is beyond the scope of the Ambulatory Cardiac Viewer software.

Once the binary file is saved in dedicated location on a local computer, start the Ambulatory Cardiac Viewer software if not started yet, then click “Receive” button. The software opens a standard Windows “Open” dialog box to specify name of the file containing received ECG strip and its location. Once the file is selected, click “OK” button in the dialog box.

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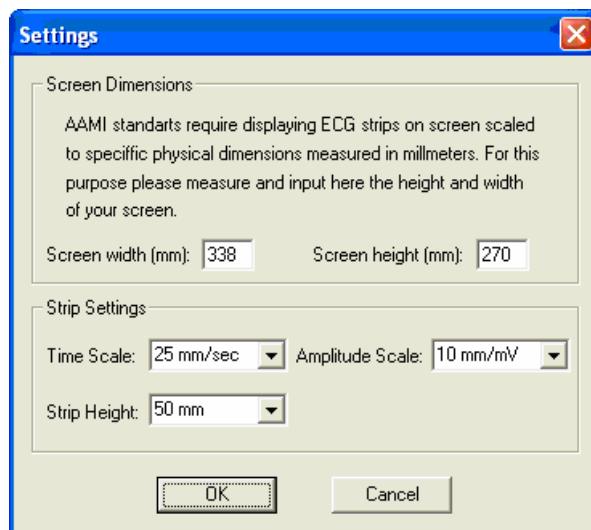
The software reads this file and adds the ECG strip to the database creating a new patient record.

Click “Cancel” button to abort adding received ECG strip to the database.

3.2.13. Configure Ambulatory Cardiac Viewer Default Settings

The Ambulatory Cardiac Viewer software operates using various system settings that are configured to specific default values.

To configure default settings click “Settings” menu option in the top screen menu. The following dialog box appears:



The AAMI standards require displaying ECG strips on computer screen in very specific physical dimensions, e.g. the total height of the strip must be precisely 50 mm, the ECG signal must be shown in certain scales (see below).

This requirement forces to use specific information about screen physical dimensions in connection to its current resolution. Modern monitors are unable to supply such information by the software requests. Because of that you should measure physical dimensions of the viewable part of the screen and input measurements into the software.

Type the screen width and height in millimeters.

Set a default strip height to one of the following options:

- 30 mm
- 50 mm

Set a default Time (Horizontal) Scale to one of the following options:

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- 12.5 mm/sec
- 25 mm/sec
- 50 mm/sec

Set a default Amplitude (Vertical) Scale to one of the following options:

- 5 mm/mV
- 10 mm/mV
- 20 mm/mV (not available if strip height is set to 30 mm)

Click “OK” button to store and enable new default settings and return to main screen.

Click “Cancel” button to drop current changes in default settings and return to main screen.

3.2.14. View Ambulatory Cardiac Viewer Onscreen Help

The software has built-in quick help describing all important aspects of the system functioning.

Select “Help” menu item from the top screen menu to open a standard Windows help window.

The help system has a table of content, from which you can open any help topic.

3.2.15. Exit Ambulatory Cardiac Viewer Software

Select “Exit” menu item from the top screen menu to close the software.

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4. ECG Monitoring

This section describes the process of using the Ambulatory Cardiac Recorder to monitor the lead II ECG of a patient. It ties together all of the steps necessary to provide a high quality signal.

4.1. Device inspection

The components of the Ambulatory Cardiac Recorder should be inspected on a regular basis and prior to each use. These inspections are important in order to guarantee the proper working condition of your system.

Perform the following steps to inspect the Ambulatory Cardiac Recorder:

1. Inspect the physical condition. Check to ensure that cases and controls are clean and in good condition.
2. Inspect cables, connectors, and electrodes. Make sure that the ECG lead wires are attached to the Ambulatory Cardiac Recorder device input connectors according to the colors of those connectors. Inspect cables for cracks, breaks, or frayed wires. If any damage is found, replace the cables immediately.
3. Check for adequate supply of ECG electrodes. Make sure the electrodes have not exceeded their expiration date or that the packages have not been opened or damaged.
4. Make sure the Ambulatory Cardiac Recorder software is loaded on your Pocket PC handheld and that you have enough memory on SD card for recording strips. Each 30 second strip takes approximately 30,000 bytes of memory so having 300,000 bytes available is a good minimum to check for.
5. Check for the low battery indicator using the Ambulatory Cardiac Recorder software. If there is a low battery indicator, change the battery.
6. Make sure there is enough battery power remaining on your Pocket PC handheld.
7. Make sure that a new spare set of batteries is always available. Check that all batteries being used and the spare battery are not beyond their expiration date.

4.2. Lead wire and electrode connection

The Ambulatory Cardiac Recorder device has three ECG monitoring lead wires that provide the monitoring of lead II only. The lead wires and connectors are all color-coded according to the American Heart Association (AHA) standards. The following table provides a list of AHA color codes for lead II connections:

Bipolar Lead Code	Lead and Reference	Color
RA - right arm	Negative electrode	White
LA - left arm	Reference	Black

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LL - left leg	Positive electrode	Red
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The connection from Ambulatory Cardiac Recorder device to each lead wire is an industry standard single .060 pin connector. This allows you to easily replace the lead wires with other compatible lead wire cables. Make sure that the lead wire cables are inserted fully into the Ambulatory Cardiac Recorder device. Loose or poor connections can cause intermittent results including "Poor Electrode Impedance" displays in the software.

The lead wires provided with Ambulatory Cardiac Recorder device utilize standard snap connectors allowing you to use a wide variety of commercially available electrodes. For best ECG monitoring results, silver/silver chloride (Ag/AgCl) electrodes should be used with this equipment. Electrodes of dissimilar metals should not be used.

Take care when attaching or removing the lead wires and electrodes to not damage the wires or connectors.

4.3. Connection to Pocket PC handheld

The Ambulatory Cardiac Recorder device connects to a Pocket PC handheld via a Bluetooth connection automatically when ECG monitoring starts.

4.4. Patient preparation

To ensure accurate ECG monitoring, it is important that the electrodes be properly attached to the patient. Follow the instructions below to prepare the patient.

Attaching electrodes to a patient:

1. Remove all clothing from the patient's chest.
2. Prepare the patient's skin for effective electrode adhesion. Shave or clip excessive hair at the electrode site. Take care not to nick the skin. Clean and dry the skin. If ointment is on the patient's torso, use soap and water to clean the skin. Briskly wipe skin dry with a towel or gauze to mildly abrade the skin and remove oils, dirt, etc.

Note that for proper electrode adhesion never use alcohol, tincture of benzoin or antiperspirant to prepare the skin.

4.5. Monitoring

Ambulatory Cardiac Recorder should only be used with respect to local protocols determining the need for cardiac monitoring.

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When cardiac monitoring is called for, be aware that other equipment operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI) which could affect the performance of this device. RFI may result in distorted ECG displays. Avoid operating Ambulatory Cardiac Recorder near cauterizers, diathermy equipment, or cellular phones. Maintain equipment separation of at least four feet and do not rapidly key EMS radios on and off.

Monitoring procedure:

1. Remove the disposable electrodes from their package. Attach the lead wires to the electrodes and then peel off the protective backing on the electrodes. Inspect the electrodes for any obvious signs of damage. Ensure that the gel on the electrodes has not dried out. If you note damage or dry electrodes, use a new set of electrodes.
2. Place electrodes on the patient based on your local protocols for lead II placement and following AHA guidelines for RA, LA, LL placement. Avoid locating electrodes over large bones, tendons, and major muscle masses. Hold the electrode taut with both hands. Apply the electrode flat to the skin and smooth the tape outward in all directions. Do not press the center of the electrode.
3. Make sure all lead wires and cables are properly connected.
4. Put the Ambulatory Cardiac Recorder device enclosure near to the patient. Position the device so as to limit any potential strain put on the lead wires and electrodes.
5. Run the Ambulatory Cardiac Recorder software on the Pocket PC handheld. If the software detects any errors, it will display an appropriate error on the screen. Follow the information in Section 3 for using the software.

4.6. After use

There are a few things that you should do following each use of Ambulatory Cardiac Recorder.

After each patient use:

1. Discard used electrodes including electrode sets that were opened and not used. Electrodes dry out in less than 24 hours.
2. Replace the battery in the Ambulatory Cardiac Recorder device if a low battery is indicated. Make sure you have a spare battery.
3. Clean the device.
4. Inspect the device and cables for damage. Repair or replace damaged items immediately.
5. Check that the lead wires are well connected to the connectors on the Ambulatory Cardiac Recorder device.
6. Recheck disposable supplies and replace whatever is needed.

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4.7. Cleaning

The Ambulatory Cardiac Recorder device and cables should be cleaned by wiping the surface with any of the following solutions:

- Soap and water
- Quaternary ammonium compounds
- Glutaraldehyde-based cleaners
- Peroxide (peracetic acid) solutions

Contact infection control resources for any specific questions regarding cleaning procedure or protocol.

When cleaning the device, pay attention to the following:

- Do not immerse or soak the device or cables.
- Do not use bleach, bleach dilution, phenolic compounds, alcohol or abrasive agents.
- Do not steam, autoclave, or gas sterilize Self-testing and calibration.

The Ambulatory Cardiac Recorder device is continually testing itself whenever it is being used. If a self-test error is detected, it will be reported immediately and all monitoring will be stopped.

The Ambulatory Cardiac Recorder device does not require any calibration or tuning.

Appendix A. Warranty and License Agreement

Limited Warranty

HARDWARE:

MedDorna, LLC (“MedDorna”) warrants to the original end user (“Customer”) that this product will be free from defects in workmanship and materials, under normal use, for one year from the date of original purchase from MedDorna or its authorized reseller. MedDorna’s sole obligation under this express warranty shall be, at MedDorna’s option and expense, to replace the product or part with a comparable product or part, repair the product or part, or if neither repair nor replacement is reasonably available, MedDorna may, in its sole discretion, refund to Customer the purchase price paid for the product or part. Replacement products or parts may be new or reconditioned. MedDorna warrants any replaced or repaired product or part, and any hardware upgrade to which Customer is entitled under an agreement between Customer and MedDorna, for a period of ninety (90) days from shipment, or through the end of the original warranty, whichever is longer. All products or parts that are replaced become the property of MedDorna.

SOFTWARE:

MedDorna warrants to Customer that the software for this product will perform in substantial conformance to their program specifications, for a period of ninety (90) days from the date of original purchase from MedDorna or its authorized reseller. MedDorna warrants the media containing software against failure during the warranty period. No updates are provided. MedDorna does not provide any warranty for Adobe® Acrobat® Reader or any other third party applications or component software that is licensed to Customer or MedDorna by the third party. MedDorna’s sole obligation with respect to this express warranty shall be (at MedDorna’s discretion) to refund the purchase price paid by Customer for any defective software product, or to replace any defective media with software which substantially conforms to applicable MedDorna published specifications. MedDorna makes no warranty or representation that its software products will meet Customer’s requirements or will work in combination with any hardware or applications software products provided by third parties, that the operation of the software products will be uninterrupted or error free, or that all defects in the software products will be corrected.

OBTAINING WARRANTY SERVICE:

Customer must contact MedDorna Technical Support or Customer Service within the applicable warranty period to obtain warranty service authorization. Dated proof of original purchase from MedDorna or its authorized reseller will be required. MedDorna is not responsible for Customer products or parts received without a warranty service authorization. In the United States, MedDorna may ship a replacement product or part prior to receiving the original product or part (“advance exchange”). If advance exchange is not available, then the repaired product or part will be shipped as soon as reasonably possible after MedDorna receives the original product or

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part. Repaired or replacement products will be shipped to Customer at MedDorna's expense. The repair and replacement process for products or parts in locations outside the United States will vary depending on the Customer's location.

Products or parts shipped by Customer to MedDorna must be sent prepaid and packaged appropriately for safe shipment and it is recommended that they be insured or sent by a method that provides for tracking of the package. When an advance exchange is provided and Customer fails to return the original product or part to MedDorna within thirty (30) days from the date the warranty service authorization is issued, MedDorna will charge Customer the then-current published catalogue price of such product or part.

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Appendix B. Warnings

This appendix lists various warnings that should be followed when using Ambulatory Cardiac Recorder. It would be a good idea to periodically review each warning to ensure its safe use for you and your patients.

Shock or fire hazard. Do not immerse any portion of Ambulatory Cardiac Recorder device in water or other fluids. Avoid spilling any fluids on the device or accessories. Do not clean with alcohol, ketones or other flammable agents. Do not autoclave or sterilize this device or accessories.

Shock hazard. Do not disassemble Ambulatory Cardiac Recorder device. It contains no operator serviceable components and dangerous high voltages may be present.

Possible electrical interference. Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI) which could affect the performance of Ambulatory Cardiac Recorder device. RFI may result in distorted ECG displays. Avoid operating Ambulatory Cardiac Recorder device near cauterizers, diathermy equipment, or cellular phones. Maintain equipment separation of at least four feet and do not rapidly key EMS radios on and off.

Safety risk and possible equipment damage. Ambulatory Cardiac Recorder device and its accessories (including electrodes and cables) contain ferromagnetic materials. As with all ferromagnetic equipment, these products must not be used in the presence of the high magnetic field created by a Magnetic Resonance Imaging (MRI) device. The high magnetic field created by an MRI device will attract the equipment with a force sufficient to cause death or serious personal injury to persons between the equipment and the MRI device. This magnetic attraction may also damage the equipment. Consult the MRI manufacturer for more information.

Battery care. Only use the model of battery indicated and follow all battery labeling instructions. Install the batteries prior to the expiration indicated on the battery labeling. Follow other battery precautions and information described in Section 2.

Patient preparation. Do not use alcohol, tincture of benzoin or antiperspirant to prepare the skin.

Electrodes. Do not use electrodes that have been removed from their foil package for more than 24 hours. Do not use electrodes beyond the expiration date. Check that electrode adhesive is intact and undamaged. Follow other electrode precautions and information described in Section 4.

Possible cable damage and loss of monitoring. Improper disconnection of the ECG lead wires and serial cable may damage the wires or Ambulatory Cardiac Recorder device. This can result in loss of the ECG signal during patient care. Position all wires and cables so that they will not be pushed, snagged, or tripped over. Do not disconnect the ECG lead wire snaps from electrode

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posts or posts on testing devices by pulling on the wire. Disconnect lead wires and serial cable by pulling each connector straight out.

Improper use. Improper use of Ambulatory Cardiac Recorder may cause injury to the patient or health care provider. Only use Ambulatory Cardiac Recorder as directed in this user's manual.

Diagnostic and ST-T segment interpretation. The frequency response of Ambulatory Cardiac Recorder, the Pocket PC handheld display, and a Windows printer is of monitoring quality and does not provide the resolution required for diagnostic and ST-T segment interpretation. It is intended only for basic ECG rhythm identification.

Patient electrical isolation. To ensure patient electrical isolation, only connect Ambulatory Cardiac Recorder device to other equipment with electrically isolated circuits.

FCC Compliance. This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

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Appendix C. Troubleshooting and Technical Support

This appendix provides you with corrective actions for the most common types of problems that you might encounter while using Ambulatory Cardiac Monitor. If the suggestions in the table don't solve your problem, technical support is available from MedDorna, LLC.

Observation	Possible Cause	Corrective Action
“Ambulatory Cardiac Recorder Not Connected” status message or “not connected” status icon displayed.	Battery in Ambulatory Cardiac Recorder device is depleted or inserted backwards. No Bluetooth connection between Ambulatory Cardiac Recorder device and Pocket PC handheld.	Check battery. If battery is not charged, replace it with new, fully-charged battery. Check Bluetooth connection.
Electrode Impedance status is RED.	Poor electrode-to-patient adhesion. A lead wire snap disconnected from an electrode. A lead wire has disconnected from Ambulatory Cardiac Recorder device. Faulty electrodes.	Make sure the electrodes are adhering to the patient's skin by pressing down firmly around the edges. The skin should be wiped dry and excessive patient chest hair should be shaved or clipped in the electrode placement areas before applying electrodes. If disconnected, reconnect the electrodes. Verify that the lead wire pins are aligned and inserted fully and securely into the Ambulatory Cardiac Recorder device input connectors. Replace the electrodes with a new set.
A “Low battery” status icon is displayed.	The battery is nearing depletion.	Replace the battery immediately with a fully-charged battery.
Excess noise in the ECG signal displayed.	Outdated and/or damaged electrodes. Poor skin preparation, electrode contact or attachment. Strong electrical field present (such as radio signals). Damaged, worn-out lead-wires.	Replace electrodes. Check skin preparation and electrodes-to-patient contacts. Check for RFI. If possible, power off noise-generating equipment. Replace lead wires.

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Excessive motion.	Check for motion.
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Technical support

MedDorna, LLC provides technical support in three ways. If you uncover a problem or have a question, use the following flowchart to get help.

Check the Customer Support area on www.MedDorna.com. The latest information and frequently asked questions (FAQ) will be there.

Email your request to: support@MedDorna.com

Call MedDorna, LLC: 512-349-8860

Appendix D. Specifications

General specifications:

General specifications	Overall size	
Height:	1.1"	
Width:	2.7"	
Length	4.4"	
Weight:	136 gram	
Battery:	2 NiMH Rechargeable Batteries, AA Size	Panasonic HHR-3CPA,2300 mAH or compatible
Power consumption (operating mode):	50 mA	
Power consumption (standby mode):	15 mA	
ECG processing specifications		
Number of ECG channels	1	
Type of Interface	Bluetooth v1.1 compliant	0.05 Hz 2POL HP Firmware, 0.05Hz 2POL HP Software, 100Hz 4POL LP Hardware
Frequency response:	0.05Hz to 100Hz 0.1 Hz 2POL HP 0.5 Hz 2POL HP 1 Hz 2POL HP, 40Hz 2POL LP	
Software Filters		
Common mode rejection:	106 dB	
Input impedance:	>40 Mohms	
Input dynamic range:	±5 mV	
DC offset correction:	±300 mV	
A-to-D sampling rate:	500 samples/sec 17 Bit at ±300 mV, 12 Bit at ±5 mV Input	
A-to-D Resolution		
Electrode impedance control	Yes	
Notch Filter	50/60 Hz	Software selectable
ECG horizontal scales (mm/sec):	12.5, 25, 50	
ECG vertical scales (mm/mV):	5, 10, 20	
QRS detection range	30-240 ±2% ?	
Defibrillator protection Circuit	Yes	
Environmental specifications		
Operating temperature	0°C - 45°C	
Storage temperature	-20°C - 65°C	
Relative humidity	10% - 95%	
Ambient air pressure	700 - 1060 millibars	
Shock and vibration	AAMI EC38.4.2.1.2	
Electromagnetic compatibility	FCC ID: SX5-EKG20100 Section 15.247, 15.205, 15.208 Section 15.109	Transmitter Portion Receiver Portion
FCC		

Title of Document

EMC	EN 60601-1-2
	AAMI ES1, IEC/EN
Electrical Safety	60601-1

Leads-off sensing and noise suppression

Ambulatory Cardiac Recorder device is designed to intentionally apply a current to the patient for the purpose of leads-off sensing and noise suppression. Three different signals are applied to the patient. All signals comply with ANSI/AAMI ES1-1985 (Safe current limits for electro-medical apparatus). Signal 1 and 2 is used for impedance measurement and leads off detection (LL and RA): 110 mV, 0.14 uA, 25 kHz square wave. Signal 3 is used for noise suppression (LA): ± 5 V max following the common mode noise present on LL and RA, <10 uA to 2 kHz and <20 uA above 2 kHz, 0-500 kHz.

Tall T-wave rejection capability

The maximum T-wave amplitude allowed for which heart rate indication is within the error limits of AAMI EC13 is 1.2 mV.

Irregular rhythm response

Ambulatory Cardiac Recorder device only responds to larger R and S waves when detecting QRS complexes. Irregular rhythms such as bigeminy / trigeminy (slow, rapid, or alternating) will not count every QRS complex.

Response time of heart rate meter

The average time required for Ambulatory Cardiac Recorder device to indicate a new heart rate for a step increase from 80 to 120 bpm is 4 seconds (tested range is between 3 and 4 seconds). The average time required to indicate a step decrease from 80 to 40 bpm is 6 seconds (tested range is between 4 and 7 seconds).

Pacemaker pulse rejection

Ambulatory Cardiac Recorder device will detect pacemaker pulses per AAMI EC13 specifications and display them on the screen. However, Ambulatory Cardiac Recorder device will not reject the pacemaker pulse from the ECG signal display. This can result in QRS detection based on the pacemaker pulse alone. Because of this, Ambulatory Cardiac Recorder device may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon the heart rate display. Keep pacemaker patients under close surveillance.